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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/341,227	08/27/99	DURR H	BAYER10184-K

HM22/0321

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EXAMINER	
SISSON, B	
ART UNIT	**PAPER NUMBER**
1655	8

DATE MAILED: 03/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

1- File Copy

Office Action Summary

Application No.	Applicant(s)
09/341,227	Hansjorg Durr et al.
Examiner	**Group Art Unit**
Bradley L. Sisson	1655

☒ Responsive to communication(s) filed on 7 Jul 1999

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-12 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-12 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Group 1650, Art Unit 1655, and has been assigned to Primary Examiner Bradley L. Sisson.

Drawings

2. The drawings are objected to for reasons as stated on FORM PTO-948 (Rev. 8-98). Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

Specification

3. The disclosure is objected to because of the following informalities: At page 23, lines 7-8, the following passage is found: "No significant fluorescence was injectable from any sample in the second injection." (Emphasis added) n Perhaps applicant had intended the first occurrence of "injectable" to read --detected--.

Appropriate correction is required.

Claim Rejections - 35 USC § 101/112

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 9-12 are provides for the use of a device, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 9-12 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

7. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (a) a method of isolating nucleic acids on a PCTE membrane in conjunction with performing capillary electrophoresis using a single capillary; and (b) a single capillary device

comprising a PCTE, does not reasonably provide enablement for the isolation and concentration of other macromolecules and life forms nor for the further processing of same nor does the specification enable other devices. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The method relates to the "isolation and concentration of macromolecules" through electrokinetic means. The "macromolecules" can be nucleic acids, viruses, proteins, bacteria, and fungi (claim 2). The specification sets forth but one reproducible method and that being directed to the isolation/concentration of nucleic acids; see pages 21-24 of the specification. While the specification has been found to contain numerous suggestions that other "macromolecules" can be isolated and concentrated, the specification has no been found to provide sufficient detail as to just how these "macromolecules" are to be isolated under different conditions using any type of membrane. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
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> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement,

> that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research.

8. The specification has not been found to enable the making and use of any device that could be used in such a method. The specification contains statements that the device is to be automated, however, the specification has not been found to enable any automated means as nor software has been filed with the application nor has a flow chart been found which addressed the flow of decisions that the software would be required to perform. The specification has not been found to enable a device that is comprised of microcassette, e.g., a chip module, and/or a plurality of interconnecting channels. The art recognizes numerous difficulties associated with junctions in a device intended for fluid manipulation. As set forth in Shartle et al., (US Patent 5,230,866):

> A number of factors contribute to the instability of the junction. For example, variations in the sample physical properties (such as density, viscosity, hematocrit, microheterogeneity, surface tension, and contact angle with housing wall) can affect both the forward pressure acting to favor flow and the back pressure available at the

> stop-flow junction to stop flow. Density controls the hydrostatic pressure at the junction. Surface tension and contact angle determine the pressure that the junction can exert in opposition to flow. Viscosity determines the rate at which the sample moves to the junction and therefore the excess back pressure (over that necessary for an equilibrium state) required to prevent the momentum of the sample from breaking through the junction. Hematocrit of blood sample affects both viscosity and density. Microheterogeneity has an impact on local properties at the junction, which can vary significantly from the bulk properties of the sample. Other variations include sample volume, which affects hydrostatic pressure by varying the height of the upper sample surface above the junction; method of sample application by different uses [*sic*; users] (or by the same user at different times); variation from lot to lot of the physical properties, such as contact angle with a standard liquid, of the housing out of which the diluter is made; variations in the size and shape of the junction arising during manufacturing, such as can be caused by plastic "burrs" at corners and edges, and local external factors, such as mechanical vibrations caused by nearby machinery of the diluter from a horizontal operating position.

It is clear that the device is intended to be used under a variety of samples so to isolate and concentrate a variety of "macromolecules." The claims also encompass a device that is to be used in the specific binding of macromolecules, including hybridization reactions, as well as modification of said macromolecules through enzymatic action or other chemical modification. The specification does not set forth in sufficient detail the elements of such a device, nor the manner in which such could be constructed and used, such that any macromolecule, including life forms, could be isolated and concentrated. Accordingly, applicant is urged to consider narrowing the scope of the claims to those embodiments that are adequately supported by the disclosure.

9. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The use of a capillary device that has incorporated therein a PCTE membrane is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by

the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Applicant is urged to consider adding the above identified limitation to the claims.

10. Claims 6 and 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As presently worded, the device of claim 6 can comprise but 1 capillary. Accordingly, it is not readily apparent how a single capillary can meet the limitation that the capillaries be "side-by-side." Claims 7 and 9-12, which depend from said claim 6, fail to t overcome this issue and are similarly indefinite.

11. The term "shallow" in claim 8 is a relative term which renders the claim indefinite. The term "shallow" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. from 5 p.m. to Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7230.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

B. L. Sisson

BRADLEY L. SISSON
PRIMARY EXAMINER
GROUP ~~1800~~ 1650
3/18/00